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### Remarks/Arguments:

#### I. Introduction

Upon entry of the present amendment, claims 12-18 will remain pending in this application. Claim 12 has been amended to clarify that the casein covers and form a protective coating that substantially encapsulates the core. Claims 19-21 have been cancelled without prejudice. Based on the following remarks, Applicants respectfully request reconsideration and allowance of the pending claims.

#### II. 35 U.S.C. § 103

The Examiner has rejected claims 12-17 under 35 U.S.C. § 103(a) as being unpatentable over Nuwayser (U.S. Patent No. 5,648,097) in view of Corrigan et al. (WO 99/03451). The Examiner's position is that it would have been obvious for one of ordinary skill in the art to use the casein disclosed by Corrigan et al. in conjunction with the calcium phosphate particles disclosed by Nuwayser. Applicants respectfully traverse the rejection and request reconsideration and withdrawal thereof.

##### A. No motivation to combine the cited references

First, there is no motivation to combine the Nuwayser particles with the casein of Corrigan because the Nuwayser patent specifically teaches that "it is a further object of the invention to develop novel mineral microparticles which are capable of degrading or eroding in a simple manner." Col. 2, lines 25-30. This disclosure directly teaches away from coating the particles to prevent their erosion so that they may be delivered orally, which is what Applicants claim. It is well known that particles intended for oral delivery

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should **not** degrade in a simple manner because the stomach acids would act on the particles before they have a chance to act.

As the Examiner knows, prior art must be considered in its entirety, including disclosures that teach away from the claims. MPEP 2141.02. In this case, the Nuwayser patent teaches away from the claimed invention because it describes injectable delivery at length and suggests that the particles should degrade or erode in a simple manner. There is nowhere in this disclosure that would motivate one of ordinary skill in the art to seek out the casein of the Corrigan and combine it with the Nuwayser particles. The Examiner has also failed to explain what the motivation would be for one of ordinary skill in the art to attempt to deliver the Nuwayser particles orally. In short, there is no teaching or suggestion in either cited reference to coat calcium phosphate particles in order to prevent them from being broken down by stomach acids. As the Federal Circuit recently stated in *In re Kahn*, 441 F. 3d 997, 986 (Fed. Cir. 2006):

Most inventions arise from a combination of old elements and each element may often be found in the prior art. However, mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole. Rather, to establish a *prima facie* case of obviousness based on a combination of elements disclosed in the prior art, the Board **must articulate the basis on which it concludes that it would have been obvious to make the claimed invention**. In practice, this requires that the Board “explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious.” This entails consideration of both the “scope and content of the prior art” and “level of ordinary skill in the pertinent art” aspects of the *Graham* test.

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**PETITION FOR EXTENSION OF TIME**

Pursuant to 37 C.F.R. 1.136(a), Applicant petitions that the period for response to the Office Action dated January 30, 2006, in connection with the above-identified application be extended for one month, to and including May 30, 2006. A credit card authorization for the fee for this petition is enclosed. The Commissioner is hereby authorized to charge any additional fees or credit any overpayment to Deposit Order Account No. 11-0855.

Respectfully submitted,

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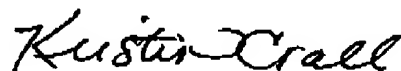
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### CONCLUSION

For at least the above reasons, Applicant respectfully requests allowance of claims 12-18 and issuance of a patent containing these claims in due course. If there remain any additional issues to be addressed, the Examiner is invited to contact the undersigned attorney at 404.815.6147.

Respectfully submitted,



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protective coat surrounding the CAP-therapeutic agent particles. The casein of Corrigan does not encapsulate the core, nor is there any teaching or suggestion to do so.

Accordingly, neither Corrigan or Nuwayser nor their combination disclose a calcium phosphate core, a therapeutic agent associated with the core; and a layer comprising casein that covers and forms a protective coating that substantially encapsulates the core, as presently claimed. Because the references, alone or in combination, do not teach or suggest each limitation of claims 12-18, Applicants respectfully request reconsideration of the current rejections and reconsideration thereof. For at least these reasons, Applicants respectfully request the Examiner to reconsider and withdraw the rejections to the pending claims.

### **III. 35 U.S.C. § 103, 2<sup>nd</sup> paragraph**

The Examiner has also stated that claims 12-17 are indefinite because it is unclear how a partial covering of casein can encapsulate a core, when encapsulation means "encase." In an abundance of cooperation, Applicants have removed that phrase "at least partially" from claim 12, although they submit that a coating or encapsulation of casein having slight nicks or holes could still be considered a protective coating that substantially encapsulates the core. The purpose for the use of the term "substantially" is to prevent a potential infringer from developing particles with very slight openings in the coating (e.g., a particle that is 95-99% coated, but not necessarily 100% coated) from arguing that their particles fall outside the claimed particles. However, it is clear from the specification and the claims, that a substantial coating (i.e., much more of the particle is coated than not) is intended.

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When the Board does not explain the motivation, or the suggestion or teaching, that would have led the skilled artisan at the time of the invention to the claimed combination as a whole, we infer that the Board used hindsight to conclude that the invention was obvious. The “motivation-suggestion-teaching” requirement protects against the entry of hindsight into the obviousness analysis, a problem which § 103 was meant to confront.

However, this is just the type of unallowed hindsight analysis that the Examiner is using in the present case.

**B. Even if combined, the claimed invention would not result**

The Nuwayser patent does not teach or disclose the claimed particles. First, claim 12 recites that the particles are delivered orally. The Nuwayser particles, on the other hand, are not described as (nor are they designed to be) delivered orally. They are “useful as injectable (parenteral) or implantable, bioerodible delivery systems” Col. 2, lines 25-30. The specification further describes how the particles can be delivered through parenteral injection and how suitable the particles are for injectable delivery. *See, generally*, Nuwayser col. 4. Thus, even if the calcium phosphate of Nuwayser is combined with the casein of Corrigan, the claimed invention would not result.

Second, Corrigan specifically indicates that its invention is for use with active ingredients that have gastrointestinal irritating effects. *See* page 5. Its particles are made by mixing and compression, granulation processes, spray drying or freeze drying the components together. By contrast, Applicants’ particles are produced by reconstructing casein micelles around therapeutic agent-loaded CAP particles for the purpose of creating a